UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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***In re:* ZYPREXA PRODUCTS LIABILITY LITIGATION**

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THE STATE OF CONNECTICUT

Plaintiff,

-against-

ELI LILLY & CO.,

Defendant.

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MEMORANDUM AND ORDER

04-MD-1596 (JBW)
08-CV-955 (JBW)

ROANNE L. MANN, UNITED STATES MAGISTRATE JUDGE:

On September 24, 2008, this Court ordered the States of Connecticut, Louisiana, Mississippi, Montana and New Mexico (collectively, "the States") "to produce a randomly selected, statistically significant sample of [Medicaid] patient medical records[,]" and to "meet and confer in good faith [with defendant Eli Lilly & Company ("Lilly")] as to what constitutes a statistically significant sample, to reach agreement on the language of a protective order, as well as to resolve any other logistical concerns they might have." In re Zyprexa Prods. Liab. Litig., No. 04-MD-1596 (JBW) (RLM), 2008 WL 4415259, at *9 (E.D.N.Y. Sept. 24, 2008). The States filed objections and, on October 21, 2008, the Honorable Jack B. Weinstein affirmed the order, but stayed its operation for thirty days to "permit the parties and any other persons to consult on settlement and other matters."[1] 10/21/08 Order, D.E. # 111, at 6.

[1] Pursuant to Judge Weinstein's order, "[a]ny party may request a further extension of the stay." See 10/21/08 Order, ECF Docket Entry ("D.E.") # 111, at 6. In addition to affirming (continued…)

This Court's order requiring production of patient medical records having been affirmed, the issue of the number of records to be produced, at least as to Connecticut, is now ripe for resolution.[2] Because the parties have been unable to reach agreement as to what constitutes a statistically significant sample, the Court is constrained to rule on that issue. For the reasons that follow, Connecticut shall produce a randomly selected sample of Medicaid patient medical records in accordance with the procedures set forth in this Order.

BACKGROUND

On September 18, 2008, this Court ordered the parties to file, by September 29, 2008, status reports regarding the progress of discovery in this case. See Case Management Order 4(A) ("CMO 4(A)"), D.E. # 85, at 1. This Court's order requiring production of the medical records intervened.

The status reports filed by the parties revealed that they had been unable to agree on the number of patient records to be produced. Connecticut proposed that it "issue subpoenas to ten randomly selected physicians for the records of up to five patients per physician but that

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[1](…continued)
this Court's order that Medicaid patient medical records must be produced by the States, Judge Weinstein appointed a Special Settlement Master to assist the parties in resolving these cases. See id. at 6-7.

Unless otherwise noted, all citations to ECF docket entries refer to those in State of Connecticut v. Eli Lilly & Co., No. 08-CV-955 (JBW) (E.D.N.Y.).

[2] Lilly maintains that it needs a complete Medicaid claims database from each state in order to determine the number of medical records it requires to defend these cases. See, e.g., Transcript of Proceedings Held on October 1, 2008 ("10/1/08 Tr."), D.E. # 96, at 177-78. As of the Court's most recent conference with the parties, only Connecticut had fully completed production of its Medicaid database.

Lilly bear responsibility for all enforcement, follow-up, and costs associated with the subpoenas and production."[3] 9/29/08 Pl.'s Status Report, D.E. # 90, at 3. Lilly's proposal, supported by the affidavit of Dr. Beth A. Virnig, an epidemiologist, indicated that it would need approximately 8,040 patients' records to investigate the issue of medical necessity; an additional 1,200 to 1,500 patients' records to investigate issues related to the development of diabetes by Zyprexa users; and thirty patient records for each of the ten to twenty Connecticut prescribers it intends to depose. See 9/29/08 Def.'s Status Report, D.E. # 92, Ex. A, Affidavit of Beth A. Virnig, M.D. ("Virnig Aff.") ¶¶ C.12, C.16 - C.17. Dr. Virnig assumed that there would be some overlap between these categories. See id. ¶¶ C.16 - C.17.

At a court hearing held on October 1, 2008, Lilly, by way of clarification, explained that it intends to use the medical records primarily to draw comparisons between Zyprexa and other atypical anti-psychotics, so that it can defend against claims by the States that other atypical anti-psychotics are cheaper, safer, and as or more effective than Zyprexa. See 10/1/08 Tr., D.E. # 96, at 59. Connecticut proposed production of between twenty-five and fifty records for the purpose of cross-checking the Medicaid claims database for accuracy, but agreed that if the records were produced for the purposes Lilly articulated, "many thousands of medical records" would be required. Id. at 63; see also id. at 64-66. An extensive colloquy ensued between the Court and the parties as to whether a narrowing of the State's claims would

[3] Connecticut alternatively proposed "that Lilly subpoena the records of as many physicians as it wishes and bear responsibility for all enforcement, follow-up, and costs associated with the subpoenas[.]" 9/29/08 Pl.'s Status Report, D.E. # 90, at 3. This Court's order requiring production of medical records, however, specifically rejected subpoenaing by Lilly as the mechanism for production. See In re Zyprexa Prods. Liab. Litig., 2008 WL 4415259, at *6-9.

reduce the number of patients' records required by Lilly. The Court instructed Lilly to "sharpen [its] pencils . . . and try to come up with the smallest number" of records it would find satisfactory, taking into account any effect a narrowing of claims by the States might have on the ultimate number of records required. Id. at 177.

Lilly sharpened its pencils, and refined its calculations. See generally 10/10/08 Def.'s Status Report, D.E. # 98. Significantly, Lilly reduced by half the number of patients' records required to draw safety and efficacy comparisons between Zyprexa and other atypical anti-psychotics. See id. at 6 & n.12. In addition, Lilly indicated that if the States would dismiss their increased-cost-of-care claims, Lilly would no longer require additional records concerning diabetic patients, and would limit the first category of records to those maintained by mental health providers. See id. at 3.

Connecticut has neither narrowed its claims nor provided the Court with a counter-proposal to that offered by Lilly. Instead, Connecticut has submitted the affidavits of Professor Meredith Rosenthal and Dr. John Abramson,[4] which primarily address why the evidentiary value of medical records is lower than that of Medicaid claims data. See generally Letter from Lauren G. Barnes, Counsel for the State of Connecticut, to the Court (Oct. 14, 2008), D.E. # 103, Ex. A, Affidavit of Meredith Rosenthal; id., Ex. B, Affidavit of John Abramson, M.D.

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[4] The Rosenthal and Abramson affidavits were submitted to Judge Weinstein in connection with the States' objections to this Court's order requiring the States to produce Medicaid patient medical records. The States filed the affidavits under separate cover with this Court, suggesting that they might "assist [the Court] in more fully understanding the strengths and weaknesses of the time-consuming and costly discovery Lilly insists on taking in these State Attorney General actions[.]" Letter from Lauren G. Barnes, Counsel for the State of Connecticut, to the Court (Oct. 14, 2008), D.E. # 103, at 1.

The Rosenthal and Abramson affidavits do not address the issue of how many records constitute a statistically significant sample.

DISCUSSION

I. Patient Records for Use in Drawing Comparisons Between Zyprexa and Other Atypical Anti-Psychotics

Dr. Virnig's affidavit states that Lilly will need 268 patient records per subgroup of interest to make the relevant comparisons regarding the medical necessity of Zyprexa. See Virnig Aff. ¶ C.11. The above-referenced number of 8,040 records results from multiplying the number 268 by thirty subgroups of interest. See id. ¶ C.12. The thirty subgroups are derived from multiplying three treatment groups (schizophrenia, bipolar disorder, and "other") by ten medication groups (Zyprexa only, Risperdal only, Seroquel only, Haldol only, and Trilafon only, with five additional "combination groups" comprised of patients who have taken one of the aforementioned medications along with at least one other medication during the relevant time period). See id. Since the filing of Dr. Virnig's affidavit, Lilly has eliminated the combination groups, reducing the total number of medication groups to five, and the total number of subgroups of interest to fifteen. See 10/10/08 Def.'s Status Report, D.E. # 98, at 6 & n.12. Lilly has also indicated, however, that if the States intend to focus their claims on specific off-label uses of Zyprexa, it would need to expand the "other" treatment group into specific categories, which would result in an increase in the total number of subgroups. See id. at 6.

In addition to the patient records described above, Dr. Virnig indicates that Lilly will need a sample of 226 diabetics per subgroup. See Virnig Aff. ¶¶ C.16. As previously

mentioned, there will be some overlap between the groups. See id.

There are some 110,000 individuals in the Connecticut Medicaid population who used Zyprexa, other atypical anti-psychotics, and/or diabetes medications. See 10/1/08 Tr., D.E. # 96, at 65-66. In light of that fact, Lilly's request is relatively modest. Further, Connecticut's damages could amount to billions of dollars. As Judge Weinstein has recognized, "[i]f you make such huge claims, the defendants are going to defend, and they're entitled to defend, and we can't deny [them] due process." Transcript of Proceedings Held on October 17, 2008, In re Zyprexa Prods. Liab. Litig., No. 04-MD-1596 (JBW) (E.D.N.Y.), D.E. # 1944, at 61-62.

To be sure, the production of thousands of medical records will be burdensome. But "[t]he fact that production of documents would be burdensome and expensive and would hamper the party's business operations may not be a reason for refusing to order production of relevant documents[.]" 7 James Wm. Moore et al., Moore's Federal Practice § 34.14[3] (3d ed. 1997). This is especially true where, as here, the party seeking discovery will bear the costs of production. See In re Zyprexa Prods. Liab. Litig., 2008 WL 4415259, at *9.

II. Patient Records for Use in Prescriber Depositions

Dr. Virnig also asserts that Lilly will need the records of thirty patients for each of the ten to twenty Connecticut prescribers it intends to depose. See Virnig Aff. ¶ C.17. But other than a conclusory assertion that Lilly needs thirty patients' records in order "to have a sufficiently representative record to effectively question [prescribers] about their treatment experience[,]" id., Dr. Virnig's affidavit contains no explanation as to how she arrived at that number.

Notably, Dr. Virnig also suggests that the "number [of patient records] may be lower if

doctors with smaller populations of antipsychotic using patients are deposed." Id. Dr. Virnig's affidavit indicates that nearly eighty-five percent of the 14,279 physicians who have prescribed atypical anti-psychotics to Medicaid recipients in Connecticut have prescribed to fewer than twenty-five patients. See id. ¶ D.3. Considering that the overwhelming majority of atypical anti-psychotic prescribers participating in Connecticut's Medicaid system prescribed to fewer than thirty patients, it is unclear why Lilly fixates on that number. Moreover, given that the depositions are limited to four hours each, it is highly unlikely that Lilly will have time to engage in extensive questioning regarding the care of specific patients.

Lilly has not provided this Court with a sufficient basis to grant its request for thirty patient record per prescriber it intends to depose. In fact, it is not clear why Lilly needs *any* patient records to question prescribers about their general treatment experience with atypical anti-psychotics, save perhaps for anecdotal purposes. Accordingly, Lilly shall be allowed to discover the medical records of fifteen patients per prescriber it deposes. These patients' records will be limited to those maintained by the prescribers Lilly deposes, and will not include records relating to the same patients but maintained by other providers. In addition, the records shall be chosen randomly, except that, if practicable, Lilly should make use of any records produced in connection with the other samplings.

CONCLUSION

For the foregoing reasons, Connecticut shall produce the medical records of 268 patients for each subgroup implicated by its expert report.[5] For this sampling ("the first

[5] The States' expert reports, including those of Connecticut, must be served by November 20, (continued…)

draw"), the number of subgroups shall be determined by multiplying the three treatment groups (schizophrenia, bipolar disorder, and "other") by the number of medication groups implicated by Connecticut's expert reports.[6] Should Connecticut choose to target specific off-label uses of Zyprexa, as opposed to off-label uses generally, the number of treatment groups will need to be expanded.

Connecticut shall further produce a sampling of the records of 226 diabetics per subgroup ("the second draw"), discounted by the number of diabetics selected during the first draw. If Connecticut abandons its increased-cost-of-care claims, and stipulates that it will not compare the incidence of diabetes among Zyprexa users with that among users of other atypical anti-psychotics, then this portion of the Court's order would become moot; additionally, the records produced in the first draw would be limited to records maintained by mental health providers.

Finally, as previously discussed, Lilly is entitled to the medical records of fifteen patients per prescriber it deposes. If practicable, Lilly should make use of any records produced in the first and second draws so as to reduce the total number of records required.

Connecticut's expert report shall indicate the comparisons it intends to draw at trial

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[5](…continued)
2008. See CMO 4(A), D.E. # 85, at 2.

[6] To take an example, if Connecticut intends to draw comparisons between Zyprexa and Risperdal only, and does not intend to target any specific off-label uses, then Connecticut would be required to produce the records of 1,608 patients in the first draw. This number would include 268 records from the following six subgroups: (1) Zyprexa/schizophrenia, (2) Zyprexa/bipolar disorder, (3) Zyprexa/other, (4) Risperdal/schizophrenia, (5) Risperdal/bipolar disorder, and (6) Risperdal/other.

between Zyprexa and other atypical anti-psychotics. Immediately following the service of Connecticut's expert report, the parties shall meet and confer to apply this Order and set the number of records to be produced.

This Order is stayed until November 20, 2008, the deadline for service of Connecticut's expert report, or until the expiration of the stay issued in Judge Weinstein's October 21, 2008 order, whichever is longer.

SO ORDERED.

Dated: Brooklyn, New York
October 27, 2008

ROANNE L. MANN
UNITED STATES MAGISTRATE JUDGE